DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 27 1999

NADA 141-084

Guy L. Tebbit, Ph. D.
Vice President, Research & Development
Regulatory Affairs and Professional Services
Novartis Animal Health, US, Inc.
3200 Northline Avenue, Suite 300
Greensboro, NC 27408

Dear Dr. Tebbit:

We refer to your Drug Experience Reports dated March 17, 22 and April 8, 1999, for Sentinel (milbemycin oxime and lufenuron) Tablets, NADA 141-084. The submissions include several promotional pieces which are deemed to be violative. Specifically, they are; 1) Detailer, coded "SFT 980039A", 2) Mouse pad, entitled "Are you giving your dog the best protection?", 3) Detailer, coded "SFT 990003A", 4) Direct mailers for dog lover sample, titled "Your dog's life could be in danger", and 5) PETsMART bag Stuffer, coded "SENH 368".

All of the above listed pieces are deemed labeling which fail to include fairly balanced risk and benefit information in the body of their text. Being determined as labeling, these pieces must include a full disclosure information, i.e., a reproduction of the package insert rather than a brief summary as required under 21 CFR 201.105(d)(1). In addition, these pieces are misleading because they represent or suggest that the product is effective in a broad range of conditions which is not consistent with the approved labeling. For example, the claim is made for the control of flea infestations, when in fact the approved claim reads, "Lufenuron controls flea *population* by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas."

Aside from these violative labeling pieces, we have also observed your advertisements appearing in various journals, magazines, etc. for various prescription drug products, all deemed to be in violation of 21 CFR Part 202.1(e)(5)(ii) of the regulations because they fail to present fair balance in their running texts. The information relating to the effectiveness of the product is presented in greater scope, depth or detail and not fairly balanced by a presentation of true information and summary relating to caution, precaution, and adverse reactions.

Additionally, we find the brief summaries in these advertisements to be unsatisfactory. They fail to present information with a prominence and readability reasonably comparable with the presentation of information in the body of the advertisement, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, etc.

Furthermore, your firm failed to submit certain promotional pieces at the time of their initial dissemination/publication as required under 21 CFR 510.300(b)(3). The material was submitted on March 22, 1999, only after receiving a phone call from our staff member on March 17, 1999. We wish to call your attention to the provisions of Section 512(e)(2)(A) and 21 CFR 510.300(d) which state that if the applicant has failed to establish a system for maintaining required records or has repeatedly failed to maintain such records or to make reports, the commissioner shall after due notice and opportunity for a hearing to the applicant, issue an order withdrawing approval of the application.

We request that you should give due consideration and attention to the promotional practices of your firm and ensure that your promotional material comply with the requirements of the Act and the attendant regulations. We ask that the dissemination of promotional material cited in this letter and other similar material being used or intended to be used in the future be *immediately* stopped.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356 V, that you will promote your products only in accord with the labeling provided for in the approved application.

We expect your response within 15 days of receipt of this letter. Should you wish to meet with us to discuss this matter, we will be glad to arrange for such a meeting. You may contact us at (301) 827-6642.

Sincerely yours

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and Regulatory Review Team II, HFV-216
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